35 U.S.C. § 112

Claim 11 stands rejected under 35 U.S.C. § 112 for allegedly being "vague and indefinite because it is unclear how a porous surface is relative to the therapeutic material." Claim 11 has been amended by removing the word relative and now recites that "the first inflatable balloon is porous [relative] to the therapeutic being delivered." The undersigned submits that this modification should obviate any alleged need to reject the claim under 35 U.S.C. § 112.

35 U.S.C. § 102

Claims 1-7, 9, 11-18, and 20-25 stand rejected under 35 U.S.C. § 102 in view of three U.S. patents. The undersigned submits that none of these cited patents disclose or suggest a hyper-deformable balloon as recited and further clarified in the claims and, therefore, that each of the claims are patentable over the cited references.

The first cited reference is U.S. patent 5,102,402, which is entitled "Releasable Coatings On Balloon Catheters." Consistent with its title, this patent is directed to coatings that are released from a balloon catheter. The abstract of this patent provides a broad overview as it states that "[b]alloon catheters are prepared to include a coating of body chemicals on the exterior of the balloon. The coating releases from the balloon when the balloon is inflated into contact with the lumen to be treated."

The undersigned submits that the '402 patent does not disclose or suggest an "inflatable balloon being hyper-deformable such that in an expanded state the first inflatable balloon replicates the irregular interior vessel surface," which is substantially recited in each of the independent claims. In the '402 patent the therapeutic is released from the balloon during the expansion process. This release may be facilitated by micro-capsules becoming liberated from the exterior of the balloon as well as by the micro-capsules exploding when the balloon expands. *See, e.g.*, col. 2. lns 33-34 and col. 5, ln. 8. This released therapeutic is then free to migrate and fill fissures that may exist in the vessel. Comparatively, in the recited claim language, the balloon is hyper-deformable and replicates the irregular surface of the vessel in order to deliver therapeutic directly to the wall of the vessel. At least based on this distinction, the undersigned submits that each of the claims rejected over the '402 patent are, in fact, patentably distinct from it.

The second cited reference is U.S. patent 6,132,397, which is entitled "Integral Aortic Arch Infusion Clamp Catheter." This patent is also true to its title and regards an aortic clamp. The abstract states that it is "[a]n integral aortic arch infusion clamp catheter (10, 90) suited to occlude the ascending aorta, infuse blood, and deliver cardioplegia solution on opposing sides of an inflated balloon (56)." The undersigned submits that, like the '402 patent, the '397 patent also fails to disclose or suggest an "inflatable balloon being hyper-deformable such that in an expanded state the first inflatable balloon replicates the irregular interior vessel surface." In the '397 patent, the expanding balloon is used as a clamp to arrest blood flow through the aorta. The balloon in the '397 patent is not hyper-deformable as it does not replicate an irregular interior surface of a lumen. Rather, the undersigned submits that the balloon in the '397 patent would distort an irregular interior surface of the lumen as it expanded and applied force against the surface to seal off the vessel. Therefore, at least based on this distinction, each of the claims rejected over the '397 patent are, in fact, patentably distinct from it.

The third cited reference is U.S. patent 5,213,576, which is entitled "Therapeutic Porous Balloon Catheter." The '576 patent regards concentric balloons placed on the distal end of a catheter. The abstract of the '576 patent states that it is "[a] balloon catheter compris[ing] a catheter shaft, and first and second balloons carried on the catheter shaft with the second balloon positioned to at least partly overlie and sealingly enclose the first balloon." The '576 patent states that "[a]s is typical for angioplasty...[the balloons] are preferably made of flexible but relatively non-elastomeric material." Col. 2, lns. 45-47. Therefore, the '576 patent regards conventional non-elastomeric angioplasty balloon technology and does not disclose or suggest hyper-deformable balloons that replicate an irregular vessel wall as in each of the recited claims. Accordingly, it, too, does not anticipate any of the pending claims.

35 U.S.C. § 103

Claims 8-10 and 19 were rejected as being unpatentable under 35 U.S.C. § 103. Because each of the additional two references cited in the 35 U.S.C. § 103 rejection also fail to suggest or disclose the above recited claim language, the undersigned submits that these claims, like the others, are also patentably distinct from these two additional references.

CONCLUSION

It is respectfully submitted that the foregoing amendments and remarks demonstrate that the application is in condition for allowance and prompt notification thereof is solicited. The Examiner is invited to contact the undersigned at (202) 220-4311 to discuss any matter concerning this application.

The Office is authorized to charge any fees associated with this Response to Deposit Account No. 11-0600.

A "Paper With Markings To Show Changes Made" is attached hereto.

Respectfully submitted,

Dated: May 16, 2002 By: _____

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Version with markings to show changes made

IN THE CLAIMS:

Please substitute the amended claims below for the pending claims with the same claim numbers. In the version below, deletion is shown by cross-through and insertion is shown by underlining.

Please amend claims 1, 11, 12, 13, 19 and 20 as follows:

1. (Amended) A system for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a source of fluid in communication with the internal lumen of the catheter; and

a first inflatable balloon having an exterior surface,

the first inflatable balloon in communication with the internal lumen of the catheter,

the first inflatable balloon being hyper-deformable such that in an expanded state the first inflatable balloon replicates the irregular interior vessel surface, and

the exterior surface of the first inflatable balloon in communication with a therapeutic when the first inflatable balloon is in an expanded state.

11. (Amended) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is porous ~~relative~~ to the therapeutic being delivered.

12. (Amended) A device for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a hyper-deformable inflatable balloon in fluid communication with the internal lumen of the catheter,

the hyper-deformable inflatable balloon adapted to replicate the irregular interior vessel surface when the balloon is in an expanded state,

the hyper-deformable inflatable balloon having an exterior surface and an interior surface;

a source of fluid in fluid communication with the internal lumen; and

a fluid pump in fluid communication with the source of fluid.

13. (Amended) The device of claim 12 wherein ~~the exterior~~ a surface of the hyper-deformable inflatable balloon ~~is in contact with a therapeutic~~ contains grooves sized to increase the deformability of the inflatable balloon.

19. (Amended) The device of claim 12 wherein the hyper-deformable inflatable balloon is made with a grooved ~~latex~~ material.

20. (Amended) A method for delivering therapeutic to an irregular interior vessel surface of a patient comprising:

inserting an expandable hyper-deformable membrane into the vessel of the patient, the expandable hyper-deformable membrane having an exterior surface;

positioning the expandable hyper-deformable membrane at an irregular interior surface of the vessel within the patient; and

forcing fluid into the expandable hyper-deformable membrane to expand the expandable hyper-deformable membrane, the expandable hyper-deformable membrane becoming juxtaposed to and replicating the irregular interior surface of the vessel of the patient.